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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.          |
|---|-------------|----------------------|---------------------|---------------------------|
| 10/568,086  | 02/13/2006  | Hans Hallstadius     | 05049.0006          | 7479                      |
| 22852   | 7590        | 01/29/2009           | EXAMINER            |                           |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER<br>LLP<br>901 NEW YORK AVENUE, NW<br>WASHINGTON, DC 20001-4413 |             |                      |                     | CHRISTIAN, MARJORIE ELLEN |
| ART UNIT  |             | PAPER NUMBER         |                     |                           |
| 1797  |             |                      |                     |                           |
| MAIL DATE   |             | DELIVERY MODE        |                     |                           |
| 01/29/2009  |             | PAPER                |                     |                           |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/568,086             | HALLSTADIUS ET AL.  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | MARJORIE CHRISTIAN     | 1797                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 January 2009.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.  
 4a) Of the above claim(s) 16-27 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/13/2006 &amp; 5/9/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Summary***

1. This is the initial Office action based on the application filed February 13<sup>th</sup>, 2006.
2. Claims 1-15 are pending and have been fully considered, claims 16-27 have been withdrawn from consideration.

### ***Election/Restrictions***

3. Applicant's election with traverse of claims 1-15 in the reply filed on January 8<sup>th</sup>, 2009 is acknowledged. The traversal is on the grounds that SCHMIDTKE has not disclosed:
  - "an apparatus for hemodialysis, hemofiltration hemodiafiltration or peritoneal dialysis"; and
  - "dialysis and/or infusion fluid".

This is not found persuasive, for the following reason: the recitation "an apparatus for hemodialysis, hemofiltration hemodiafiltration or peritoneal dialysis" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481

(CCPA 1951). Further, SCHMIDTKE discloses a "dialysis and/or infusion fluid" in Col. 3, Lines 43-45.

The requirement is still deemed proper and is therefore made FINAL.

***Priority***

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 102***

5. **Claims 1, 4-6, 12, 15 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,156,002, POLASCHEGG et al. (hereinafter POLASCHEGG).**

As to Claims 1, 4, 15, POLASCHEGG discloses an apparatus for hemodialysis (Fig. 1), comprising a conduit in which a dialysis infusion fluid is intended to flow (10), comprising a measurement unit (172) for measuring at least one substance in said fluid by measuring the influence on a polarized beam of light transmitted through the fluid (C7/L1-14, Claim 16), where the concentration of said substance above 100g/L is the material worked upon and does not limit the apparatus. As it has been held that "expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In*

*re Young, 75 F.2d \*>996<, 25 USPQ 69 (CCPA 1935) (as restated in In re Otto, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).*

As to Claims 5-6, POLASCHEGG discloses the measurement unit is designed to measure the concentration of glucose (C7/L1-5).

As to Claim 12, POLASCHEGG discloses a container housing a fluid (186), wherein the container is connected to the apparatus to allow the fluid housed in the container to be fed to the apparatus (Fig. 3), and said measurement unit (172) is arranged to measure the concentration of said substance in the fluid fed from the container.

#### ***Claim Rejections - 35 USC § 103***

6. **Claims 2-3 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 6,156,002, POLASCHEGG et al. (hereinafter POLASCHEGG) in view of US Patent No. 6,139,748, ERICSON et al. (hereinafter ERICSON).**

As to Claim 2, POLASCHEGG discloses the measurement unit for the optically active substance in hemodialysis apparatus as shown in the 102(b) rejection of Claim 1. POLASCHEGG does not appear to expressly disclose that the measurement unit measures said substance before fluid is mixed with other matters. However, ERICSON discloses a plurality of inlets for different matters (Fig. 1, Refs. 3-5), said different matters being mixed with each other (2) after being introduced via said inlets (3-5), where it is implicit that the concentration of the substance is measured prior to being mixed with other different matters introduced via different inlets and it would be obvious

to a person having ordinary skill in the art to use the measurement unit of POLASCHEGG as it measures concentrations of glucose (C7/L1-5).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the hemodialysis apparatus of POLASCHEGG to include the plurality of inlets and mixing of ERICSON. The motivation would have been to provide concentration of glucose that mimics normal blood concentrations (C1/L17-28).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 3, ERICSON discloses a first inlet (3) for introducing the fluid to be measured into the apparatus (2) and it would be obvious to a person having ordinary skill in the art to measure the substance with the measurement unit of POLASCHEGG configured such that it measures the concentration before being mixed in the apparatus (2) with any other different matters introduced via another of said plurality of inlets (4, 5), as it is implicit that the concentration of the substance is measured (known) prior to being mixed.

7. **Claims 7-11 are rejected under 35 U.S.C. 103(a) as being anticipated by US Patent No. 6,156,002, POLASCHEGG et al. (hereinafter POLASCHEGG) in view of US Patent No. 5,457,535 SCHMIDTKE et al. (hereinafter SCHMIDTKE).**

As to Claim 7, POLASCHEGG discloses measuring the concentration of a substance in a hemodialysis apparatus. POLASCHEGG does not appear to explicitly disclose generating a warning if the measured concentration does not fulfill a

predetermined requirement. However, SCHMIDTKE discloses means arranged to generate a warning signal if the measured concentration of said substance in said fluid does not fulfill a predetermined requirement (SCHMIDTKE, Claim 10, Ref. 39a).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the optical sensor of POLASCHEGG to include the warning signal of SCHMIDTKE. The motivation would have been to accurately measure the concentration of optically active substances (C1/L52-58) and avoid exceeding a threshold value of detected stray light which interferes with measurement (C7/L23-27). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claim 8, SCHMIDTKE discloses a partly transparent conduit in said apparatus (C3/L32-37), configured to carry the fluid to be measured (C3/L38-50), wherein said measurement unit is configured to produce a polarized beam of light that is passed through the fluid to be measured at the conduit (Abstract).

As to Claim 9, SCHMIDTKE discloses said measurement unit is arranged to provide a plane-polarized beam of light (Abstract, Refs. 1, 21, 23, 31, 36).

As to Claim 10, SCHMIDTKE discloses a measurement device to measure an entity (Abstract), said entity indicating the angle at which the plane of polarization of said polarized beam of light has rotated when the polarized beam of light has passed through the fluid (C5/L4-31, Ref. 39).

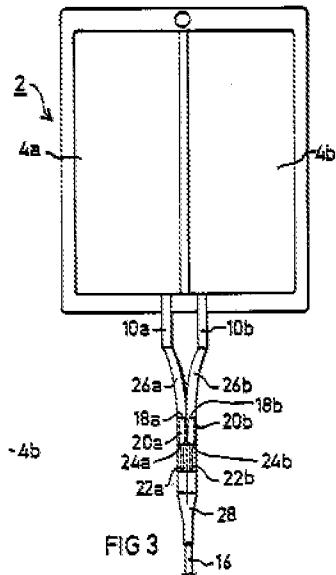
As to Claim 11, SCHMIDTKE discloses a light intensity detector (54, 64).

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8. **Claims 13-14 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 6,156,002, POLASCHEGG et al. (hereinafter POLASCHEGG) in view of WO95/08299 TOBE et al. (hereinafter TOBE).**

As to Claim 13, POLASCHEGG discloses the container of fluid to be measured as shown in the 102(b) rejection of Claim 12. POLASCHEGG does not appear to expressly disclose the container includes first and second compartments. However, TOBE discloses the container (Fig. 3, Ref. 2) includes first (4a) and second compartments (4b) having contents, the contents of the compartments being mixed before the fluid leaves the container (28).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the container of fluid of POLASCHEGG to include the first and second compartments of TOBE. The motivation would have been to have an assembly that can easily and safely mix liquids in a single operation (Pg. 2, Lines 27-31). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.



As to Claim 14, TOBE discloses the container is a flexible fluid bag (Pg. 3, Line 7).

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: WO2004/070323, HALLSTADIUS et al. as it discloses a sensor device for measuring concentrations in fluid flow.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MC

/Krishnan S Menon/

Primary Examiner, Art Unit 1797